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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,322	10/24/2006	Mesut Muyan	21108.0032U2	9900

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NEEDLE & ROSENBERG, P.C.  
SUITE 1000  
999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

EXAMINER
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BURKHART, MICHAEL D

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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08/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/574,322

Applicant(s)

MUYAN ET AL.

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9, 11-13, 15-23, 30, 50, 51, 55, 58-61, 64, 67-86, 88, 90, 92 and 94 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-5, 7-9, 11-13, 15-23, 30, 50, 51, 55, 58-61, 64, 67-86, 88, 90, 92, and 94 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Note: claims 90 and 94 are dependent from a canceled claim (claim 87), hence, they have been restricted based upon dependence from claim 1.

Group I, claim(s) 1, 2, 7-9, 11-13, 15-23, 30, 86, 88, 90, 92 and 94, drawn to a composition comprising first and second DNA binding domains separated by a hinge domain.

Group II, claim(s) 3 (in part) and 50, 51, 55, 58 and 59, drawn to a composition comprising a first and second DNA binding domains separated by a hinge domain, and further comprising an activation domain.

Group III, claim(s) 4 and 5, drawn to a hinge domain.

Group IV, claim(s) 3 (in part) and 60, 61, 64, 67 and 68, drawn to a composition comprising a first and second DNA binding domains separated by a hinge domain, and further comprising a repressor domain.

Group V, claim(s) 69-71 and 73, drawn to a nucleic acid encoding the composition of Group I, vectors, and cells comprising the nucleic acid.

Group VI, claim(s) 72 and 74, drawn to animals comprising the cells of Group V.

Group VII, claim(s) 75, drawn to a method of identifying a gene under control of a hormone response element by contacting a cell with the composition of Group I.

Group VIII, claim(s) 76, drawn to a method of identifying a gene under control of a hormone response element by contacting a cell with the composition of Group II.

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Group IX, claim(s) 77, drawn to a method of identifying a gene under control of a hormone response element by contacting a cell with the composition of Group IV.

Group X, claim(s) 78 and 84, drawn to a method of treating cancer by administration of the composition of Group I.

Group XI, claim(s) 79, drawn to a method of treating cancer by administration of the composition of Group IV.

Group XII, claim(s) 80-82, drawn to methods of inhibiting the transcription of a gene by contacting a cell with the composition of Group IV.

Group XIII, claim(s) 83, drawn to a method of overexpressing a gene in a cell by contacting the gene with the composition of Group II.

Group XIV, claim(s) 85, drawn to a method of treating cancer by administration of the composition of Group II.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups I, II, and IV-XIV is a composition comprising first and second DNA binding domains separated by a hinge domain, said composition also binding a DNA binding site. However, Muyan et al (Mol. Cell. Endocrinology, 2001) disclose in Fig. 1A an endrogen receptor homodimer fusion protein that comprises two C domains (DNA binding domains) separated by a D domain (a hinge domain by applicants definition, see page 37 and Fig. 1A of the instant disclosure). The ER homodimer fusion protein of Muyan et al bound the ERE DNA sequence, see Fig. 1D.

Therefore, the technical feature(s) linking the inventions of Groups I, II, and IV-XIV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group III is considered to be a composition consisting of a hinge domain. This special technical feature is not found within or used by the other Groups.

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Furthermore, if Group I is elected, the Group is subject to further restriction as follows. The SEQ ID NOs listed in Group I are subject to an additional restriction since they do not share a special technical feature. Claims 16-19 and 30 recite the DNA binding sites of SEQ ID NOs 1-22. Claims 86, 88 and 90 recite the DNA binding domains of SEQ ID NOs 23, 25, 27, 29, 31, 33, 35, 37, or 39. Claims 92 and 94 recite the hinge domains of SEQ ID NOs 24, 26, 28, 30, 32, 34, 36, 38, or 40. None of the sequences share a common structure (sequence) or function. Although these sequences are disclosed as being derived from hormone receptors and their respective DNA response elements, they are considered to be unrelated, since each sequence is structurally and functionally independent and distinct for the following reasons: each has a unique amino acid or nucleotide sequence (i.e. structure), each recognizes a distinct ligand (e.g. estrogen, progesterone) or is linked to the expression of distinct genes, and therefore each has a distinct function. As such, the above sequences each have a special technical feature not found in the other sequences. Furthermore, a reading of the specification reveals that each sequence is known in the prior art, and thus the sequences do not define a contribution over the prior art. In view of the foregoing, one sequence from each category is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one DNA binding domain sequence from claims 16-19, 30, 86, 88 and 90, and one hinge domain sequence from claims 92 and 94, if Group I is elected. Note this is not a species election.

Accordingly, Groups I-XIV are not so linked by the same concept or a corresponding technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhardt whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhardt  
Examiner  
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